

1. (amended) A prolonged effect therapeutic nail varnish composition comprising:

- (a) a pharmaceutically effective agent;
- (b) a humectant;
- (c) water;
- (d) less than about 7.5% of the total weight of the composition, of a polymeric film-forming agent;
- (e) at least one additional excipient; and
- (f) a solvent system, said solvent system containing at least one volatile solvent;

said film-forming agents being selected so as to form a film upon evaporation of said volatile solvent, said film configured to trap water in contact with a nail.

5. (amended) The nail varnish of claim 2, wherein said antifungal agent is present in an amount of less than about 1% of the total weight of the composition.

6. (amended) The nail varnish of claim 2, wherein said antifungal agent is present in an amount of less than about 5% of the total weight of the non-volatile components.

9. (amended) The nail varnish of claim 2, wherein said keratolytic agent is present in an amount of less than about 1% of the total weight of the composition.

10. (amended) The nail varnish of claim 2, wherein said keratolytic agent is present in an amount of from about 0.05% to about 5% of the total weight of the non-volatile components.

13. (amended) The nail varnish of claim 11, wherein said antibacterial agent is present in an amount of from about 0.01% to about 1% of the total weight of the composition.

14. (amended) The nail varnish of claim 11, wherein said antibacterial agent is present in an amount of from about 0.05% to about 5% of the total weight of the non-volatile components.

16. (amended) The nail varnish of claim 11, wherein said antiviral agent is present in an amount of from about 0.08% to about 0.8% of the total weight of the composition.

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17. (amended) The nail varnish of claim 11, wherein said antiviral agent is present in an amount of from about 0.8% to about 8% of the total weight of the non-volatile components.

19. (amended) The nail varnish of claim 11, wherein said antipsoriatic agent is present in an amount of from about 0.02% to about 2% of the total weight of the composition.

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20. (amended) The nail varnish of claim 11, wherein said antipsoriatic agent is present in an amount of from about 0.1% to about 10% of the total weight of the non-volatile components.

22. (amended) The nail varnish of claim 1, wherein said humectant is present in an amount of from about 3% to about 15% of the total weight of the composition.

23. (amended) The nail varnish of claim 1, wherein said humectant is present in an amount of from about 5% to about 35% of the total weight of the non-volatile components.

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24. (amended) The nail varnish of claim 1, wherein said water is present in an amount of less than about 5% of the total weight of the composition.

25. (amended) The nail varnish of claim 1, wherein said water is present in an amount of from about 0.4% to about 25% of the total weight of the non-volatile components.

26. (amended) The nail varnish of claim 1, wherein said polymeric film-forming agent is selected from the group consisting of hydrophobic-polymers.

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cont.

27. (amended) The nail varnish of claim 26, wherein said hydrophobic-polymer is selected from the group consisting of hydrophobic cellulose derivatives, hydrophobic methacrylic polymers, cellulose acetate phthalate, shellac, derivatives thereof, and mixtures thereof.

28. (amended) The nail varnish of claim 27, wherein said hydrophobic cellulose derivatives are hydrophobic derivatives.

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30. (amended) The nail varnish of claim 1, wherein said polymeric film-forming agent is present in an amount of from about 8% to about 35% of the total weight of the non-volatile components.

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38. (amended) The nail varnish of claim 36, wherein said plasticizer is present in an amount of from about 0.1% to about 2% of the total weight of the composition.

39. (amended) The nail varnish of claim 36, wherein said plasticizer is present in an amount of from about 0.5% to about 10% of the total weight of the non-volatile components.

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44. (amended) The nail varnish of claim 1, wherein said volatile solvent is present in an amount of from about 60% to about 90% of the total weight of the composition.

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47. (amended) A prolonged effect therapeutic nail varnish composition comprising:

- (a) an antifungal agent;
- (b) a keratolytic agent;
- (c) a humectant;
- (d) water;
- (e) a polymeric film-forming agent;
- (f) at least one additional excipient; and
- (g) a solvent system, said solvent system containing at least one volatile solvent;

*- Sub
A11
Cont.*

~~said film-forming agents being selected so as to form a film upon evaporation of said volatile solvent, said film configured to trap water in contact with a nail.~~

*A12
sub
C2*

~~50. (amended) The nail varnish of claim 47, wherein said antifungal agent is present in an amount of less than about 1% of the total weight of the composition.~~

~~51. (amended) The nail varnish of claim 47, wherein said antifungal agent is present in an amount of less than about 5% of the total weight of the non-volatile components.~~

*A13
sub
C3*

~~54. (amended) The nail varnish of claim 47, wherein said keratolytic agent is present in an amount of less than about 1% of the total weight of the composition.~~

~~55. (amended) The nail varnish of claim 47, wherein said keratolytic agent is present in an amount of from about 0.05% to about 5% of the total weight of the non-volatile components.~~

*A14
sub
C4*

~~58. (amended) The nail varnish of claim 56, wherein said antibacterial agent is present in an amount of from about 0.01% to about 1% of the total weight of the composition.~~

~~59. (amended) The nail varnish of claim 56, wherein said antibacterial agent is present in an amount of from about 0.05% to about 5% of the total weight of the non-volatile components.~~

*A15
sub
C5*

~~61. (amended) The nail varnish of claim 56, wherein said antiviral agent is present in an amount of from about 0.08% to about 0.8% of the total weight of the composition.~~

~~62. (amended) The nail varnish of claim 56, wherein said antiviral agent is present in an amount of from about 0.8% to about 8% of the total weight of the non-volatile components.~~

64. (amended) The nail varnish of claim 56, wherein said antipsoriatic agent is present in an amount of from about 0.02% to about 2% of the total weight of the composition.

Alb

65. (amended) The nail varnish of claim 56, wherein said antipsoriatic agent is present in an amount of from about 0.1% to about 10% of the total weight of the non-volatile components.

sub
C⁶

67. (amended) The nail varnish of claim 47, wherein said humectant is present in an amount of from about 3% to about 15% of the total weight of the composition.

sub
C⁷

68. (amended) The nail varnish of claim 47, wherein said humectant is present in an amount of from about 5% to about 35% of the total weight of the non-volatile components.

69. (amended) The nail varnish of claim 47, wherein said water is present in an amount of less than about 5% of the total weight of the composition.

70. (amended) The nail varnish of claim 47, wherein said water is present in an amount of from about 0.4% to about 25% of the total weight of the non-volatile components.

sub
C⁸

71. (amended) The nail varnish of claim 47, wherein said polymeric film-forming agent is selected from the group consisting of hydrophobic polymers.

72. (amended) The nail varnish of claim 71, wherein said hydrophobic-polymer is selected from the group consisting of hydrophobic cellulose derivatives, hydrophobic methacrylic polymers, cellulose acetate phthalate, shellac, derivatives thereof, and mixtures thereof.

A18
Sub a
C

75. (amended) The nail varnish of claim 47, wherein said polymeric film-forming agent is present in an amount of less than about 7.5% of the total weight of the composition.

76. (amended) The nail varnish of claim 47, wherein said polymeric film-forming agent is present in an amount of from about 8% to about 35% of the total weight of the non-volatile components.

A19
Sub
C11

84. (amended) The nail varnish of claim 82, wherein said plasticizer is present in an amount of from about 0.1% to about 2% of the total weight of the composition.

85. (amended) The nail varnish of claim 82, wherein said plasticizer is present in an amount of from about 0.5% to about 10% of the total weight of the non-volatile components.

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90. (amended) The nail varnish of claim 47, wherein said volatile solvent is present in an amount of from about 60% to about 90% of the total weight of the composition.

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Sub B5

93. (amended) A method of preparing a prolonged effect therapeutic varnish or spray formulation for treating the nail and surrounding tissues, comprising the steps of:

- (a) preparing a solution, said solution containing at least one volatile solvent;
- (b) adding water to the solution prepared in (a);
- (c) dissolving the pharmaceutically effective agents, and excipients in the solution prepared in (b);
- (d) adding the humectant to the solution prepared in (c) when the formulation ingredients are completely dissolved; and
- (e) dissolving the polymeric film forming agents in the solution prepared in (d);

said film-forming agents being selected so as to form a film upon evaporation of said volatile solvent, said film configured to trap water in contact with the nail and the surrounding tissues.